TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
DOW AGRO SCIENCES MEETING)
)

Pages: 1 through 49

Place: College Park, Maryland

Date: February 25, 2004

HERITAGE REPORTING CORPORATION
Official Reporters
1220 L Street, N.W., Suite 600
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IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
DOW AGRO SCIENCES MEETING)
)

Room 1A-001
Federal Drug Administration
5100 Paint Branch Parkway
College Park, Maryland

Wednesday,
February 25, 2004

The parties met, pursuant to the notice, at 12:06 p.m.

BEFORE: MS. CINDY SMITH

APPEARANCES:

For United States Department of Agriculture, Animal Plant Health Inspection Service, Biotechnology Regulatory Services:

REBECCA BECH, Associate Deputy Administrator
SUSAN KOEHLER
JOHN TURNER
NEIL HOFFMAN

For Arent Fox:

STANLEY H. ABRAMSON, Esquire

APPEARANCES CONTINUED:

For Dow AgroSciences:

BRADLEY A. SHURDUT, Global Director

For Dow Chemical:

R. N. MILLER, Director, Public Issues

P R O C E E D I N G S

(12:06 p.m.)

MS. SMITH: Well, welcome. We're glad you could join us here today.

This is our stakeholder discussion series on our upcoming environmental impact statement, or EIS, and our revised biotech plant regulation.

We want to thank you for taking time from your busy schedules to participate in this forum and share your thoughts here with us today.

The purpose of these briefings is twofold. First, to share information on our plans to move forward in developing an environmental impact statement, and to amend our plant biotechnology regulations. And secondly, to gather diverse, informative input which will support thoughtful and effective decision-making on our part in the development of our new regulations.

We have here, from BRS, most of the management team, as well as numerous members of our staff, and when available, other key agency personnel that are supporting BRS will be joining us as well.

I should also mention two key individuals who have now been dedicated to providing full-time management of our work to complete both the environmental impact statement and our plant biotech regulation provisions. John Turner, who

you likely know, is a very important member of our leadership team here at BRS. And I'm pleased to say that John is leading this effort on a full-time basis.

And the second individual, a face that you may not be familiar with, is Michael Wach, a recent BRS hire as an environmental protection specialist within our environmental and ecological analysis unit that Susan Koehler heads up.

In addition to possessing a Ph.D. and an Environmental Law degree, Michael brings research experience and plant pathology and weed science, as well as legal experience, working on cases involving NEPA, the Clean Air Act, the Clean Water Act, and other environmental regulations.

What I'm going to do at this point is turn this over to John, who will make some additional remarks, and then we will give the meeting to you.

MR. TURNER: As you likely know, we recently participated in interagency discussions with EPA, FDA, and the White House, which, while concluding a coordinated framework, provides appropriate science- and risk-based regulation for biotechnology, the Plant Protection Act of 2000 provides a unique opportunity for APHIS to revise its regulations, to potentially expand our authority while leveraging the experience gained through our history of regulation to enhance our regulatory framework, and position

us well for future advancements of the technology.

We also concluded those discussions with general agreement on how our biotech regulatory approach would evolve. Still, there is much opportunity for public and stakeholder input as we move forward to develop the specifics of our regulatory enhancements.

Given this, what we would like to do at these meetings is to have an opportunity to hear your thoughts, as well as have an informal give and take of ideas. We have a unique opportunity for this type of discussion, since we're not yet in the formal rule-making phase of the process. So we're free to speak freely and openly and exchange ideas with stakeholders and the public.

Our discussion will be professionally transcribed, primarily for two reasons.

First, we want an accurate record of our discussions to facilitate our ability to capture and refer to your input. And secondly, in the interest of transparency and fairness to all stakeholders, we will be making available as part of the public record, and potentially on our website, documentation on all our stakeholder discussions, so that the public and other stakeholders will have the benefit of each of the discussions that we will be conducting this week.

Of course I should emphasize that while we're

happy to share information on the direction we are likely to take during the process, and that we will be sharing our thinking in BRS, and that during the process, public and stakeholder input will likely influence our thinking.

In addition, other officials in USDA, including our Administrator, Undersecretary, Office of General Counsel, and the Secretary, can certainly be expected to provide insightful direction, as well. So while we value all input, it is important for us to recognize that our thinking will likely evolve. So while we may have enthusiastic discussion on a particular aspect of our regulation revisions, this will be an evolving process.

Finally, since it will be hard to predict what the final regulation will look like, I would like to briefly share with you overall BRS priority areas of interest to set the direction and help guide the development and implementation of the regulatory and policy strategies and operations.

Rigorous regulation, which thoroughly and appropriately evaluates and ensures safety and is supported by strong compliance and enforcement.

Transparency of the regulatory process and regulatory decision-making to stakeholders and the public, critical to public confidence.

Science-based system, ensuring that the best

science is used to support regulatory decision-making to assure safety.

Communication, coordination, and collaboration with the full range of stakeholders.

And finally, international leadership, ensuring that international biotech standards are science-based, supporting international regulatory capacity-building, and considering international implications of policy and regulatory decisions.

As we prepare to begin our discussion, I would let everyone know that for the effective transcription of our session, that all statements and questions need to be directed into a microphone. And for those who have not previously identified themselves to the transcriber, if you can state your name prior to speaking.

With that, I would like to open up the floor to hear your comments and discussion.

MR. SHURDUT: I'm just wondering, for our own edification, some faces are familiar, some not so familiar. To get an understanding of people around this room. I would be happy to tell about who we are and what we represent in the company. That would be very helpful, before we move into this.

MS. SMITH: Okay. Do you want to start?

MS. KOEHLER: Susan Koehler. I'm the Branch Chief

of the newly-created Environmental and Ecological Analysis Group -- about 1994. And you see some of the new group is here, Mike Blanchette and Michael Wach and Robyn Rose are part of that group. Did I miss anybody?

MS. SMITH: Why don't we go around and let everybody introduce themselves?

MS. BECH: I'm Rebecca Bech. I'm the Associate Deputy Administrator for BRS.

MS. SMITH: Cindy Smith, Deputy Administrator.

MR. TURNER: John Turner, Director of Policy Coordination Division.

MR. HOFFMAN: Neil Hoffman, Director of Regulatory Programs.

MR. BLANCHETTE: Mike Blanchette, Environmental Specialist.

MR. WATSON: Mike Watson, biotechnologist.

MR. WACH: Michael Wach, Environmental Protection Specialist.

MS. BARTLEY: Laura Bartley. I'm in the Policy Division.

MS. ROSE: Robyn Rose, entomologist.

MR. WHITE: Jim White, supervisory biotechnologist.

MS. SOILEAU: Carmen Soileau, biotechnologist.

MR. ZAKARKA: Christine Zakarka. I'm from a

division in APHIS on loan to BRS for project management, planning, and support.

MR. ROSELAND: Craig Roseland, Policy Division.

MR. SHURDUT: Okay. And for your edification, I'm Brad Shurdut, located here in D.C. I'm head of government and regulatory affairs for Dow Agrosciences, really focusing on our biotech platforms within the ag side of the business.

MR. MILLER: My name is Bill Miller. I'm with the Dow Chemical Company, which is the parent of the company, Dow Agrosciences. We're a global plastic, chemicals, and agricultural science company. I'm the Director of Public Policy and Issues regarding the biotechnology. My role in the company is to work with Brad and my other colleagues who apply biotechnology in a variety of business units.

MR. SHURDUT: And with that, first of all, I appreciate the introduction. Actually, I appreciate the opportunity to meet with you guys in such a formal setting. But it's a great opportunity.

We do think, and I think a lot of what we do in Dow Agro and Dow Chemical is stakeholder dialogue with third-party input as we move forward as a business. And we think likewise that there has been tremendous leadership within APHIS over the last couple years, especially, but even before that, in trying to get broad stakeholder input, and in some respects, guidance and counsel on moving forward

with biotech.

And the process it looks like you've just started to undergo in terms of first the EIS, and then subsequently I understand moving towards rule making, I think in many respects it's a much needed look to take and really test the existing regulations that we have, not to say, from a technology provider's standpoint, that something is broken or not working, but we do think that with the new technology coming on board -- and we're probably one of the better examples of a company that probably is going to cover the waterfront in terms of the technologies -- that revisiting and looking at the regulations is always useful. It's always important to do, especially to make sure that it's grounded in sound science. It's extremely important, a thing that you guys are doing.

So we welcome this opportunity. We encourage it. And we also certainly welcome the opportunity, or like the opportunity that we're able to participate and provide our input into this.

MR. MILLER: I would only echo Brad's comments relative to our appreciation for the transparency which the agency is taking, the outreach to the variety of stakeholders which the agency is taking, and to the rigor of the process that's being put forward. We think that it's an important discussion and dialogue to have.

And while many informal discussions take place, forums such as this that are more formal also have and serve their purpose. And so we applaud the direction in all the various facets in terms of how this is going, science-based, rigorous, open communication, international in nature. We think all those are key attributes to bring the technology forward in an effective and appropriate manner.

MR. SHURDUT: And I guess, with that, I think by and large -- we can stay on the record here -- that we do support what's in your document in terms of moving forward within EIS, in terms of any amendments to the APHIS regulations. And we do have a series of questions, as we prepare our own comments, which we will officially submit to you guys, just some clarifications. You probably need it from our standpoint.

And I don't know how this discussion is going to be, but as there are questions, hopefully you can at least enlighten us to some extent, which will help us provide further direction for our comments.

I guess the first question I have is, as you move forward here, not only with this piece, but with subsequent rule-making if, in fact, it comes to that, is the inter-agency process going to be fully at play as you move forward, from the standpoint of when you look at the various dimensions? And as you know, the BT products, EPA does a

lot of the environmental, I think, you know, Robyn and others, and maybe others, came from the EPA world, where they did a lot of the environmental and ecological.

The question is, how are you going to look at potential for redundancy of what you're doing, so it doesn't slow down the process, per se, but complements the process?

MS. SMITH: That's a good point. And we've talked a lot in the inter-agency process that we used to get to this point about exactly that, how we can work in a way that is complementary to each other, rather than redundant. So it's not our intention to create additional burden, or to repeat the work that's being done elsewhere. Rather, we see ourselves leveraging these additional authorities that we're considering, and use that in partnership with the FDA and EPA to take advantage of the roles that they play and the reviews that they do.

I just had a conversation this morning with Janet Anderson about the idea of doing joint reviews in some cases, and sharing information more freely, and reducing the burden on both of our agencies, as well as those that come to us for permits. So it's not our intention to create any redundancies, but just to make sure that everything is fully covered between the agencies.

MR. SHURDUT: Okay. So it sounds like there will be that interim dialogue as you move forward with the

various pieces, okay.

And, Bill, feel free to kind of jump in here. But in terms of just getting back to the environmental piece sa we move forward, clearly we do certain things to register a BT product. And as we look forward, it's clearly going to be, it's going to take an amount of time to reorganize internally, in terms of scientific expertise, to develop certain kinds of data.

So clearly, as there's a request for additional data or more comprehensive framework, will there be, or do you anticipate a transition time to be able to do that, come up to speed, and also deliver that data? Because a number of us have, a number of the companies, including Dow, have a lot of products that are in the USDA and EPA in different parts of the process.

And so the question is, have you thought about the transition piece, and how you'll move that into the system?

MS. SMITH: We have thought a little bit about what we're going to have to take into consideration, given that. And certainly things that are in the system now won't be affected by this. But as we get closer to moving to a final goal, then we'll be in a better position to be communicating to applicants regarding implications for what may be new in the pipeline at that point, and how we'll do the transition.

When we get to the point where we put out a proposed rule, then that should give you some pretty good sense of the direction that we're heading. Of course, that will evolve based on public comment and the appropriate process. That should give you a pretty good sense of where we are, and what to expect in terms of additional requirements. But that is something that we will continue to be open to thinking about as we go through the process.

MR. MILLER: I'm looking through some of my previous notes here. I would be interested in any additional comment or clarification you might be able to provide relative to how you see the agency working with the states, going forward in the development of the regulatory framework.

Having been a lot of the work done over the years here in Washington relative to the EPA, the White House, and this organization, now there seems to be a direction into the state organization, I'd be interested in how you see that dialogue and discussion flowing.

MS. SMITH: We see that as a very appropriate dialogue, particularly as there is increasing interest at the state level, and with constituencies that are at the state level in biotech.

One thing, we have a number of strategies that we're using to work closely with the states. Yesterday

morning, for example, we met with the commissioners of each state department of agriculture, and had a discussion on a number of issues relevant to what we're doing in BRS.

One of the things that we talked about in more detail at that meeting was our intention to have a workshop, where our intention is to bring in staff-level individuals from each state department of agriculture to actually participate with us in writing our regulation. So that we can make sure that we are in a good position to really fully address what the roles of the states should be, how we're going to partner with the states, what the coordination should look like. And then, to the best of our abilities, to be able to address the issues that are being raised at the state levels, to the extent that they are appropriate to our regulation.

So that's a primary thing that we are planning to do with the states, particularly in terms of the development of this regulation.

MR. SHURDUT: I just want to, and then we can go back, but I want to talk a little bit about -- and I'm assuming you'll hear this in a number of other discussions -- but the whole issue of adventitious presence. So we're fortunate enough to see that media release a couple days ago by UCS on the whole AP thing, which in many respects, I think, remnants of that, or it's an artifact of,

not having a clear policy. At least that's our interpretation, having a clear U.S. policy on that, or even an international policy.

But you clearly need to start with a clear, cogent U.S. policy to be able to export, or even talk in terms of multi-level discussions there.

On the AP piece here, in your document you certainly defined your authorities as being much broader than they've ever been defined before. You know, given the jurisdictional reach of PPA.

With that being said, are you, and to what extent are you considering looking at AP or a potential policy move as it relates to, or scientific move towards AP within this particular effort? Or do you see that as a separate effort, and AP clearly, the early safety testing with products in the field, et cetera?

MS. SMITH: We do plan to, as indicated in our Federal Register Notice, to address AP as part of this rule. Given the expanded authorities that we have, we are in a very good position to fully address AP.

At the same time, it's one of the topics that we have to give a fair amount of discussion about. And it's something that we recognize the need to move forward as quickly as is appropriate. And we will be looking at the extent to which there's something that we can, if there is

an appropriate thing for us to come out with prior to the actual, the final rule-making.

MR. SHURDUT: Okay. So it may be part and parcel, or not necessarily connected with the overall rule-making process?

MS. SMITH: There certainly will be a long-term incorporation of adventitious presence policy in the final rule. But there might be something that is done before that; that's what we're uncertain about. But we're looking at that possibility.

MR. SHURDUT: And I'm assuming that that would be done in concert -- see, the logical inconsistency or the legal inconsistency potentially is, when you do AP, if USDA comes out with a piece there, then you have this whole issue of potential adulteration on the FDA side, or however. So I'm assuming an AP policy, you'd likely work with FDA? Would they have to be part of the equation?

MS. SMITH: You certainly would have to be in dialogue with them to ensure that, if we were in a position to do something separate to FDA, that it would have to come from what FDA does, and certainly not be contrary to anything that they were doing.

MR. SHURDUT: And what, imports with potential AP, would that be part of the scope?

MS. SMITH: We're certainly open to considering,

at this point, any possibilities. And that is something that we have talked about.

MR. SHURDUT: And clearly, from a Dow perspective, as you know, when you introduce or launch a seed in the U.S., all of a sudden you're a global player. And we do work all over the world, a lot of breeding and all that stuff. But clearly, just putting something in the U.S. commerce, it all of a sudden becomes a global commodity.

So when you look at a system in terms of U.S., it's just as important from our standpoint to look at it in terms of OUS impacts, or outside U.S. impacts, as well. And that might be a way for USDA to show some leadership, to be able to do that, and to look at sort of global systems. And to bring in some other countries into that discussion would be pretty helpful.

MS. SMITH: John, would you like to talk a little bit about your thinking for AP?

MR. TURNER: Yes. As Cindy said, certainly we view that as an integral part of the new rule. You'll see in the NOI discussion of tiered-risk assessments.

So part of that, one of the criteria -- and it may not be explicit in the NOI, but an obvious way to address it is one of the criteria to allow field testing under a more relaxed situation would be that it would have to have its early safety assessment from the FDA.

So under our expanded authority, we don't anticipate that we would be moving in, doing FDA's work. But we could consider the review status at FDA in how we impose various confinement standards. And in that way, could motivate people to go to FDA.

So you could then be in a position, the U.S., to make a statement that those things which are likely to be found at low level, intermittent levels, have had their early safety assessment. If those things have not, then we will keep extraordinary confinement standards on them. And we all know about those categories.

So that's sort of how we anticipated addressing it in the new rule. And I think I agree with you that anything that we would have to do would have to be pretty much in lockstep with FDA, it's going to be an inter-agency process. Any policy that we make, we couldn't justify having one for exports and a different one for U.S. imports. That also is part of the equation.

MR. SHURDUT: And just I guess one last, or it probably won't be the last. In AP, when you talk about the AP category, I think you kind of potentially intimated that for some products, and not for others. In terms of that adventitious presence, even opportunity to do early safety testing, what categories would that pertain to? Would it be everything? Food and feed, as well as PMPs and PMIPs,

potentially? Or what would that pertain to in terms of coverage and scope?

MR. TURNER: Certainly things that are put into food crops or on the track as food or feed, those would be -- in terms of things that would presently qualify, under notification, a lower-risk category, if they want to field-test under a similar type of condition, those would need to go to FDA.

Other things, PMPs, I don't think we're exactly clear on where those would fall. As you know, as of the March 10 notice in the Federal Register, we have some pretty drastic confinement measures that are supposed to keep those out of the food supply.

Beyond that, discussions are ongoing with the FDA as to how those should be handled with respect to an early assessment.

MS. SMITH: And certainly the August Federal OSTP, Federal Register Notice that was put out, addressed adventitious presence just in terms of food and feed crops.

MR. SHURDUT: Okay.

MR. MILLER: If I could maybe initiate a discussion on point two of the notice, regarding environmental factors that should be considered in -- in particular I want to inquire and discuss a bit about the plant pharmaceutical factors that should be considered.

First off, to date largely this has been done on a case-by-case, or a protein-by-species-type basis. We support that. We believe that's important, because of the number of variables that occur on each of the cases.

Clearly, plant characteristics, the protein of interest, the characteristics of that particular protein, the confinement measures that are required by permit, location, duration, size of the trial I think are all at a high level, very important environmental considerations to put into consideration.

I'd be interested if you could discuss further other considerations that may be in your dialogue and discussion and your thought process currently.

MR. TURNER: Well, I think you've hit the major ones, certainly size of the field trial, the exact nature of the compound, and its status at the other agencies, whether FDA has looked at it or not, is something that we would consider.

So one of the things I didn't mention when I was talking about categories, something might come in under the high-risk category, if we can use that term, and might move based on a review at FDA or other type of review that we do that would show it was more appropriate in a different category.

So I think the things that are on the table -- and

this is an active area of discussion and evolving -- is the crop itself. Is it a food or feed crop? The nature of the protein, its review status at the other agencies. And then any confinement measures, if there are bioconfinement measures that can be applied, all of those would be considered.

And we can talk about whether there's movement among the categories, or how much flexibility we have within a category. So that even though it may stay as a C, a high-risk category, we still might have great flexibility in the confinement standards. But we're not settled on exactly what that will look like.

MR. SHURDUT: Just going back to that one point you talked about, the AP and the PMP thing. I think just from our standpoint and the number of companies, the number of big companies that are involved with this, it keeps changing for business reasons, et cetera. But it would seem to me that Dow is one of the bigger players, more active players, in PMPs at this point in time.

We strongly, from the standpoint of AP and to erode in any way that current sort of, well, it's not scientific, 100-percent confinement or complete confinement is something that we very much, at this point in time, support the continuance of. To loosen that, to move anywhere near even the thought of a deregulation or an okay

allowable level from an AP, which tends to connote an operational standard where you can be good, but you don't have to be perfect, we think that companies should strive to be perfect and as close to 100 percent. And any allowance beyond that we feel is a mistake, not only from a public confidence standpoint. Clearly, the slippery slope is whether it can be justified from a scientific perspective.

A lot of these things will be somewhat innocuous; they are antibodies, et cetera. But we do think, just in terms of the mission of the USDA in terms of agriculture getting along with everybody else, and companies getting along, because this is a manufacturing process, we believe that the current standards and the stringent standards are appropriate, and should be maintained as much as possible.

MR. MILLER: I'd like to reinforce some of Brad's points. We believe the current --

(Interruption.)

MR. MILLER: We believe that the current advancements that the agency has made in terms of perfect conditions, the increase in inspections throughout the development cycle of a field trial from plot preparation through planting and harvest and post-harvest monitoring, we think those are all very appropriate.

The attention the agency has given to dedicated equipment, the clean procedures, the standard operating

procedures, the training of employees as a part of perfect conditions, we do believe those are all very appropriate, and continue to support them.

We have severe reservations about any softening of the permit process for PMPs or PMIPs from a variety of perspectives, not the least of which is public confidence.

We would encourage the agency to look for mechanisms to work with other agencies to prepare to deal with the unforeseen, unintended, unwanted scenario where these materials may, despite the manufacturing practices, despite a number of redundant systems, despite a vision of zero, may, by some act of God, occur and be present in food crops. Even if it's a non-food crop PMP, it somehow could find its way into a food crop.

So we encourage and are open to discussion and dialogue with this agency and with the FDA that, how all affected parties could provide information into a mechanism such that in the, again, unwanted, unforeseen, and unlikely event that this would occur, that all the parties have some reliable information to react to, to react with, to respond with, to minimize destruction on all of the stakeholders, be it the regulatory agencies, tech providers, the food/feed value chain, consumers as a whole, or the medical community.

So be open to those considerations as these new rules are considered and thought through.

MR. TURNER: I sort of had a follow-up question for you guys.

If we didn't consider any softening of the standards and loosening of the regulations in cases where the science does not suggest a risk, but the public perception issue is still high, which will be the case for some pharmaceuticals, do you see an issue for APHIS in those situations in seeing that our standards are science-based?

MR. MILLER: I think it's a great question, and it's one we wrestle with, as well. We strongly support, as a science- and technology-based company, we strongly support science-based regulation. And yet, I think many of us have come to learn over time that public perception has a significant consideration here. And it maybe is not so much a matter of if you can do these things, it's maybe a matter of when, based on the ability of the public to see the technology developed, to gain confidence in the regulatory process, to better understand how the technology is being applied. For the public to better feel directly the positive impact of the technology and its benefits.

Then there may come a point in time, and it may be different across the spectrum of applications, when a science, a preponderance of the science-based considerations should be brought forward. PMPs would be a classic example today.

The paradigm of pharmaceutical production is not understood by many in the food/feed value chain, let alone in the general public, of what this industry is trying to become. It's not clearly understood by the public as to the length of time before some of these products will become available, and the direct benefits will be seen. The scope, the scale, and a number of the regulatory requirements that are already in place are not well understood. And thus, as a result of the lack of that understanding, the public opinion is on one side of the equation rather than the other.

Through efforts such as this, the transparency and the outreach that not only the agency is doing, but the industry is doing, I think over time will reach a point where, while very important considerations -- health consideration is always very important -- the ability to consider whether or not some of the science piece considerations will take us maybe in a slightly different direction than we're headed right now. I think that time will come. I don't know that it's now, and I think we actually may do the technology a long-term disservice by moving too quickly in that direction.

MR. SHURDUT: And just to add to that, as Bill pointed out, it is sort of a conundrum in terms of how you deal with it. But when you look at it, it's been a long

time since I've been in the traditional manufacturing part of Dow. But when you look at the way you manage a site, you know, you do have permit requirements and that. And a lot of times you are held to zero emissions, you know. Everything else may be science-based, but there are operational guidelines that don't always need to be based on science.

In certain cases, if our effluents are still innocuous, you are still held to, you know, zero emissions on certain things. So there are a fair amount of analogies, at least from an operational standard, in terms of containment and how you do business, that could answer or go a long way to answering these sound, scientifically-based concerns. You know, based on that this is a manufacturing process. That has to be considered as part of the equation.

The other piece, if you did allow it, I don't know how, and maybe you can help me understand how at all the USDA is going to link with the trade interests. You know, are you going to have USTRs and FAS and everything else that, you know, trade is a big issue. I'm assuming if you haven't, you've probably heard by trade interests, the grain folks, a lot of our stuff, most of our stuff in some cases go overseas. But how that figures into the process, and how the USDA considers that.

But also, if you allow any of it out at this point

in time, FDA has many times over affirmed or confirmed that if it's in there, and it's not intended for food and feed, it would be, per se, adulteration. So if the standards become lax and there is some ability to release it, then you have another agency that potentially may consider that, per se, adulteration.

We tend to believe that it's not always per se adulteration, based on the type of product. But you do have that intergovernmental piece that would fly in the face potentially of USDA loosening their standards, without resolving the larger interagency piece here.

MS. SMITH: I should clarify that it would not be our intention to move in a direction, unless FDA was moving in that direction.

MR. MILLER: As I look down the other elements, I've flagged a couple others. One is point six. If I understand this correctly, there is a consideration of more of a notification -- and correct me if I'm wrong -- there is a consideration of potentially using more of a notification type of, of products not intended for food or feed, like PMPs, that were developed under confinement. Is that the proper interpretation?

MS. SMITH: No. Actually what we're talking about under number six is whether we should consider establishing a separate mechanism for long-term production of

pharmaceuticals and industrials. Is there a better mechanism than simply applying for permits year after year, if, as you move into the commercialization phase of pharmaceutical and industrial production, you may essentially be doing the same.

MR. MILLER: I understand, okay. So if, in fact, we have a PMP or PMIP plot or a growing region, whatever, essentially producing the same material from the same hybrid, under the same conditions, on an ongoing basis or a multiple-iteration basis, would that permit have an extension period?

MS. SMITH: Yes, that would be part of it. And other things, as well. We want to give special or appropriate consideration to any issues that we may want to consider should perhaps be handled slightly differently. Another example would be transparency. Can we have a mechanism that is more transparent, while it respects confidential business information?

I think there is more of an expectation from the public, or an interest from the public, to understand what's being grown in terms of pharmaceutical and industrial crops, as well as the confinement measures that guarantee the safety of those crops.

And so what we might be also talking about in the area of transparency is, is there some additional

information that would be related to that mechanism, whatever mechanism we put together, that communicates both what it is that's being tested and the confinement measures that are in place.

MR. MILLER: And the other one I had here is maybe a little too narrow a focus, but point 11 has to do with containers. And I would ask that the agency consider performance-based specifications for containers for these materials, rather than a physical specification. Such that the expectation is that if it has certain performance standards, it can withstand a drop from a four-foot trailer bed or it can withstand a four-foot drop, or whatever. Rather than a physical specification that it must be made out of this kind of material, with this physical size and geometry, and so on and so forth.

Because of the breadth of different plant materials being used, and the different site locations and different operational procedures that the tech providers will be using and are using, I think a performance-based approach to what the expectation is would be more workable, and deliver the positive result that the regulation is intended for, rather than a prescriptive definition of what the container needs to physically look like. I'd ask you to consider that, as well.

MS. SMITH: We're certainly open to considering

that.

MR. SHURDUT: Taking this in a little bit of a different direction, in here, I just need a little bit of clarity, there is doing this type of bio-farmer work as in plants that are being grown out in the environment, the ones in the greenhouse. There is also certainly the opportunity and the potential to do things with plant cells.

If you do a drug or a pharmaceutical with plant cells, it could go to CVM, or it could go more in the traditional side of things, whether it be FDA or it could be CVB if it's an animal health drug. One thing that we hope at least you'd consider is, there has been a long history of industry working with CVB and others on developing a pretty tight process around these sort of fermentation-based systems that use plant cells, et cetera. And I don't know whether you've given any thought as to how what you're doing may potentially affect that, given that a lot of that's been bolted down pretty tightly in terms of the requirements and how to move forward.

But I don't know if you have any thoughts about how that may play in here, if you're using a plant cell versus a plant, whether it would go to CVB versus APHIS. Because I don't see a whole lot of distinction between the whole plant-versus-cell in this piece here.

MS. KOEHLER: Can I ask a clarifying question

there? Are you saying that APHIS should consider regulating plant cells and fermenters for production of PMPs?

MR. SHURDUT: No. I am suggesting that, because that more mirrors the true biotechnology, the pharmaceutical biotechnology, and it's probably further along to developmental process within USDA, within the CVB group, that by mistake, and/or because there is not enough attention to it, you don't retard or somehow interfere with that separate process that's been moving forward on a parallel effort.

Because when you talk about plants and non-viable material and everything else, it doesn't take long before you unknowingly touch upon other processes and other operations that USDA deals with. So it's more or less to bring to your attention, and perhaps maybe it's necessary to consult with the CVB folks if that hasn't already been done.

MS. SMITH: Thank you.

MR. TURNER: That's very helpful.

MR. MILLER: The technology, while over the last several years has brought the technology forward, the definition kind of was viewed to be open-field pollinated crops, and in particular, corn.

As we continue to work with the technology, we see a breadth of host systems, we see a breadth of operational systems, some of which are open-field, some of which are

greenhouse-based, some of which are in fermenters and variations there of growth chambers.

And so, I guess it would be our recommendation that as these additional technologies get further defined and developed, we reflect upon the existing set of rules and regulations -- CVB being a good example -- where these things likely are already being addressed so as to avoid redundancy and to leverage the existing routes to regulation.

And one other area you talked about earlier, if I recall, but I want to make sure I understand. In point five APHIS is considering the regulation of non-viable plant material. Can you help me better understand the scale of which that is at? Is it at the DNA level, or what-have-you, in soil? Or at the macro level of, you know, leaf tissue in the field? Where is the scope here?

MS. SMITH: Actually, all we're doing at this point is just acknowledging that within the expanded authorities of the Protection Act, we have the ability to look at plant products, rather than our historic, you know, something had to be viable material. So at this point all we're doing is just putting that out there, that that's something that we would have the authority to do, and we're asking for comments to help us determine if that's something that we should consider. And if we did, what would that

look like.

MR. SHURDUT: Another area just to kind of quickly touch upon is, a lot of this is focused on transgenic regulation. But it also puts in nuances of regulating based on novelty. You know, it's a novel product, a new product, it hasn't been seen before.

Have you given any thought -- clearly, there's technology out there available where it's novel crops that are non-transgenic, done through non-transgenic means? We also know the National Academy of Sciences has touched upon that in some of their discussions around USD and their procedure. But any thoughts about the regulation of non-transgenic? And again, I am not advocating that be done. But do you anticipate that that could fall within the scope of what you're trying to do here? And have you thought about that?

MS. SMITH: I would tell you we've thought about it. And as we look at structuring a system, the enviable place we're in now is kind of allowing ourselves to say what is the prefect system. So we're looking at all kinds of options in that realm. And of course, one of the things that comes up is, you know, what's going on not through genetic engineering, but novel.

So it's something that we have thought about this, because that's kind of our business to be thinking about the

fuller picture. I wouldn't suggest at this point that that is something that is under, that we see that within our ability. I think we'll have to be open to what kinds of comments that we get through this process.

But I'll just say we're aware of that as one issue. But it's not something that's under, that we have any heavily serious conclusions about.

MR. SHURDUT: Okay. And by the nature of our questions, you can understand where we're at. I mean, there are a lot of companies that are looking at, for whatever the reason is or motivation, to move away from transgenics, per se, whether it be public policy or whatever the reason is. But there's also a slippery slope, because you do get in what's novel, and you look at just regular hybrid technology. That does fit into the category, what we've done for hundreds of years.

MS. SMITH: It's a good issue.

MR. SHURDUT: Yes, okay. Let's go down and see if we have all the clarifications we need.

You talked about in some cases, and this is kind of reverting back to our earlier discussion, moving into that whole deregulation, and even PMPs or PMIPs, there may be that day, if they go through the appropriate food safety review. Any thoughts about what that food safety, if you ever talked about moving PMPs in that direction, what that

food safety review is, or would look like? Is it a food additive review? Any thoughts? I mean, food safety reviews are all over the place in this document. And what's kind of your definition of food safety review for the various categories?

MS. SMITH: That's a good question. I think what we have -- I think largely what we've talked about so far internally is starting with what kind of role FDA can play in terms of their evaluation, and honoring whatever information can be brought to us through a process with FDA. But that's something that still needs more discussion. So we're open to any comments in that area.

MR. SHURDUT: Sure, absolutely. But clearly, you know, one thing that we feel needs to be considered -- and again, it depends on whether it's food and feed crops -- to go through a food, even an early food safety testing review, there are obviously certain things that you can do at certain levels, depending on your level of development, where you are. Volume, quantity, getting protein, we're constantly fighting the battle of delivering data, whether it be here or AP or whatever, we're getting the protein, enough protein, to do what we need to do.

And so usually you need some surrogate data or digestibility testing or something. But that there be consideration, and the right question to ask back from USDA

and the government to the industry, in terms of what's possible at the various developmental stages, given that, you know, doing animal testing. It's hard to do that early on in the developmental process, given the lack of protein. So it's kind of a thing we think about, and we constantly think about when we talk about AP and early safety testing. Sounds great, but is it possible?

MS. SMITH: And we've had those very similar discussions here, as well.

MR. MILLER: And in the spirit of the PMPs, in the spirit of pharmaceutical paradigm, which the tech providers are advancing those technologies, and to my earlier comments, we would encourage the ability for tech providers to provide information into the agencies about the safety of these materials as they're being developed.

In that spirit of pharmaceutical paradigm, I'm not sure I would categorize it as a food safety documentation or submission, but rather a safety assessment, or a health assessment. Some delineation for the public, for the other stakeholders, as well as tech providers, that these materials are not intended for food or feed. The information you may need to assess a BT product for food or feed safety, it would likely be different than the information they want for PMP or PMIP.

And so conceptually, you know, they're headed to

the same end point. But how we define them, how we not only define them in terms of the activity, but define them in terms of what is required, what makes them valuable and beneficial I think could be worthy of some consideration and some delineation to keep this paradigm of pharmaceutical production versus agricultural commodity production in the forefront.

MR. SHURDUT: And even to add to that, I think you brought up even earlier, is on the PMP side, to at least think through some mechanism where, again, you heard our view about thinking the full, complete containment or confinement is the way to go here, when that act of God or something happens. Frankly, it doesn't even take anything to happen; it's just an allegation from a group that they found something. That the need to have something really, and not having something today really threatens, you know, our future as just the freedom to operate.

And the discussion about platform four and doing all that, with, again, not to throw those in, but we've obviously had history in the aggie area of having products get into the food supply, and then it's taken years at that time to resolve it.

Some proactive thinking about what if, in case, having safety data on hand, et cetera, would be extremely important. And I think will guide, even short-term, how far

and how fast we continue with PMPs production. Because major companies, we are about making money and limited liability. And that's just extremely important to be able to do this.

MR. MILLER: I think we are coming to the end of our comments, at least the inputs you want to provide, any questions or clarifications we wanted to ask for.

MR. SHURDUT: Just one more on my point. Again, you talked about the AP. Also, clearly from my point of view, the need for USDA to potentially look at ways or opportunities on this whole mandatory consultation. Before you do it, you mentioned earlier that you believe you have the authority to not do certain things until certain things happen. Clearly, to have food safety review on products, biotech products intended for food and feed, and that coordination with FDA continues to be important.

In the past, you know, and nor do we ever expect it to be a health issue here, but as you have new technologies, novel technologies moving forward, if you demand additional data and additional testing around the environmental piece, it only makes sense that, since your mission is also looking at the public health, that there be a mechanism to make sure that there is the proper safety testing from the human consumption standpoint, before final deregulation.

And we clearly see it as part of your mission, part of your mission in not only our culture, but public health. And anything you can do on forging that kind of discussion with FDA as part of the process under your jurisdiction would be extremely helpful. And I think at least wanted by Dow, and I'm certain other technology providers.

MR. MILLER: Any questions for us? Or areas that we can provide additional input to you on?

MS. SMITH: Okay, let's see, do we have some questions?

MS. ROSE: Obviously my question is going to be ecologically based. I wonder where Dow may see APHIS's role in monitoring potential ecological effects post-commercialization. For instance, potential population effects on non-targets, or resistance monitoring and such.

MR. SHURDUT: Yes. I mean, our position has always been not only providing the right data up front to get the products registered, clearly stewardship and ongoing effects, and being able to act when we see an effect is something that I think we welcome.

I think in the past, whether we worked with EPA or you guys or others, that's always been sort of a question of the resource-intensiveness of being able to do that. But I think we've always been, and frankly been on record that if

you want to lend a hand in terms of a surveillance piece and all that, that's part of a good overall stewardship program. And again, it will help us, you know, as we move forward, in terms of what we do with a particular product.

So we welcome it, if that's the proper way to do it, and if there's a way to do it that's cost-beneficial to do it, as well.

MR. ROSELAND: How would Dow feel about mandatory limits placed on production of PMPs? If some arbitrary figure was established?

MR. MILLER: In terms of?

MR. ROSELAND: Acreage.

MR. MILLER: Acreage. And based on trying to achieve what purpose, or based on what need?

MR. ROSELAND: Just in terms of containment efforts, success would be greater in a smaller acreage compared to a larger acreage.

MR. MILLER: Well, I don't have a ready answer for that, in terms that I'm trying to envision the situation. It potentially could limit the products that you would produce.

As an example, monoclonal antibodies is one of the most significant classes of materials that are being considered for plant-made pharmaceutical production in open field. One of the reasons that is is because many of the

indications that monoclonal antibodies are being developed for are chronic indications.

(Interruption.)

A case in point would be rheumatoid arthritis. Availability of Enbrel and other kinds of drugs that treat rheumatoid arthritis has been historic by production capacity, which has been one of the openings from which plant-made pharmaceuticals may, one of the gaps that they may fill.

But by definition, chronic diseases such as that, monoclonal antibodies, given their large size, tend to lead to large volumes. So you may have to dose, you know, a patient maybe three grams annually. With a monoclonal antibody you may have a patient population that is very large, and you may have a treatment regimen that lasts 20 or 30 years.

And so one of the classic openings for PMPs is that kind of situation, where you need additional production and the complex proteins can be provided by PMPs.

So there could be, by having, depending on the level of the restriction, if the restriction was 100 acres versus 10 acres, and given the indication that you're trying to treat -- frankly, given the point in time that that regulatory restriction may be placed on how the technology is developing. Because we personally believe that over

time, we will have greater expression rates, therefore our footprint could be managed. But if those breakthroughs don't come through at the same timetable, with the geographic limitation that might be imposed, it could be possible to limit some of the opportunities that would exist that now is being targeted at.

So it would be a consideration that would like to have some effect.

Now, having said that, I think one of the other things to consider, at least in the case of the corn that is being developed in this application, one of the possibilities that tech providers are looking at seriously is the ability to store proteins in materials like corn for an extended period of time.

So an inventory of raw material, if you will, could be stockpiled for two, three, four years, and drawn off over a period of time. So in that case again, the footprint, in the macro sense, could be reduced. You may need 100 acres in year one; you may have zero plantings in years two, three, and four.

In this scenario, you may be forced, in fact, to have 25-acre plantings each and every year. And then, from a probability perspective, you might argue I've got four more opportunities in the field before a problem, rather than one opportunity in the field before a problem.

So it is a mechanism I think that would really need a lot of consideration. Because in fact you might get an unintended result, which is you're actually in the field on a more frequent basis than a less frequent basis, even though your scale may be different.

MR. SHURDUT: Just one addition, just really getting back specifically to your question. It's just kind of a simple answer from my standpoint, is size and scale should not matter if your standards are performance-based, and if they're scientifically performance-based, no matter what the size. If your approach is 100 percent, or confinement, whatever, size, clearly the onus is on the company and what they need to do will potentially change with size.

But at the end of the day, we have to achieve the same standards, so it shouldn't matter much in terms of the overall equation.

MS. SMITH: Other questions?

MS. KOEHLER: Are there any additional measures that you think that APHIS should put into place for pharmaceuticals? For PMPs and PMIPs?

MR. MILLER: Well, the nature of the permit conditions we have received over time. And as opposed to the Federal Register here and most recently last year, I guess it was, we believe it addressed a number of the

confinement considerations. Certainly we believe in the tiered system, beginning with isolation, including biological measures, including temporal measures, gestational measures.

So I think those approaches, given a host plant and a variety of other considerations, provide a lot of flexibility in the technology to leverage, in order to get the multiple layers of containment, confinement as you desire.

I can't think of any, beyond those broad categories, that would add to that. I think within each of those, there are subsets of activities or actions or technologies you can use to achieve them. There is some physical, I mean, you could do some detasseling, you could do the male sterility. You could do greater isolation distances or lesser isolation distances. You can do greater or narrower time frames. But all of those, how you stack them, all lead to some level of high probability of confinement that I don't know of any other major mechanism that you could put into the equation that would enhance it.

The short answer is, I think you have all the major categories included in the consideration for permanent conditions today.

MR. HOFFMAN: Earlier someone mentioned the possibility of having an issue with the commingling of a

non-food crop with a food crop. And I was wondering if you want to elaborate on that. Was there a specific scenario you had in mind?

MR. MILLER: Many of the stakeholders have challenged the tech providers as to -- and I'm sure the agency, as well -- as to why are you doing this in food crop? Why not just pick a non-food crop? The presumption being that that would just make all the problems go away. And I'm not personally convinced of that.

First of all, there aren't any, thus far there have not been any really good non-food crop candidates. And people such as ourselves have looked for them. But because those non-food crops have not been cultivated for large-scale purposes, by and large, the characteristic, the understanding, the economics of those points are not as well understood. And so there are some real considerations about how viable they would be as plant hosts for this kind of technology.

There are some real considerations as to, you know, validation of the potency and effectiveness of the derivative protein by FDA, when you're using something that's not well characterized. A non-food crop may contain some things that are actually a hazard. I mean, pastures often -- you know, it raises up as, here's an industrial crop, but it has that nasty little thing called ricin in it,

which hasn't been engineered out of it, per se.

And so there's a lot of issues that don't necessarily say non-food crops solve all the issues.

Then play over on top of that, even if one were to advance a non-food crop product, depending on the considerations we have today -- the site, the location, the agronomic practices, the handling, so on and so forth -- if it was sited in a region that has a high agricultural production, traditional ag commodity, ag production and activity, and it wasn't channeled properly, it, too, could inadvertently find itself in food or feed. If the equipment wasn't dedicated, if the surveillance in post-harvest and those kinds of activities weren't the same.

So by simply moving to a non-food crop, I'm not sure I accept that all the issues that many are concerned about go away. I just think you have a different, you fundamentally have a different plant host. That's really what you've achieved. You've not necessarily advanced your separation or segregation in any significant way, and you may create more problems along with it that are unintended or unforeseen.

MS. SMITH: Other questions? Okay. Well, thank you. We really appreciate you coming in and taking time to share your thoughts with us. And we look forward to talking with you more as we go through the process.

MR. MILLER: Thank you, we appreciate your time, as well.

MR. SHURDUT: Once again, I also applaud your efforts on the long road ahead. I appreciate it.

MR. TURNER: We look forward to your written comments. It was very interesting today.

MR. MILLER: And if we can just get a transcript so we don't have to do that work all over again.

(Whereupon, at 1:23 p.m., the meeting in the above-entitled matter was adjourned.)

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REPORTER'S CERTIFICATE

CASE TITLE: DOW AGRO SCIENCES MEETING
HEARING DATE: February 25, 2004
LOCATION: College Park, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 25, 2004

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